### Missouri Statewide Health Information Exchange

Legal/Policy Workgroup: State Consent Policy Webinar

February 5, 2010 2-4 PM CT





#### **Agenda**

- 1. Welcome
- Background on Workgroup consideration of consent to date
- Brief background on legal basis & principles for consent policies
- 4. Overview of select state consent policies
- 5. NeHII Presentation
- 6. VHIE Presentation
- 7. MAeHC Presentation
- 8. Q&A
- 9. Next Steps



### Legal/Policy Workgroup – Consensus Recommendations to Date

- Some form of consent should be required to exchange information through MO's statewide HIE network.
  - Model TBD (e.g. opt-in, opt-out, etc.)
  - Workgroup to engage local counsel to advise on state law requirements.
- > Type of consent required may vary depending on use of information:
  - Sharing information for treatment and quality improvement should be first order priority.
  - Public health reporting should be enabled to the extent mandated under current law.
  - Different consent may be required for other uses.
    - Marketing
    - Use by payers
    - o Others TBD
- Regarding sensitive health information, there is a need to address heightened patient privacy concerns while facilitating the availability of necessary information at the point of care.
  - Workgroup to engage local counsel to advise on state law requirements.
  - Workgroup to coordinate with Consumer Engagement Workgroup.



#### Legal Baseline for Consent for HIE: HIPAA & State Laws

#### > HIPAA Privacy Rule

- National floor governing when and how Covered Entities may use and disclose protected health information ("PHI").
- Consumers should have some control over when and how their PHI is used.
- Patient consent not required for treatment, payment, and operations ("TPO").

#### State Laws<sup>1</sup>

- Many states have laws that regulate disclosure of general health information; some go beyond HIPAA and require consent for TPO.
- Majority of states further regulate disclosure of specific types of health information:
  - HIV/AIDS
  - Mental health
  - Substance abuse
  - Genetic testing
  - Others

See Privacy and Security Solutions for Interoperable Health Information Exchange. Report on State Law Requirements for Patient Permission to Disclose Health Information. HISPC. August 2009.



#### HHS Privacy and Security Framework Principles<sup>23</sup>

- Openness and Transparency There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their individually identifiable health information.
- Individual Choice Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their individually identifiable health information.
- Collection, Use and Disclosure Limitation Individually identifiable health information should be collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately.
- Individual Access Individuals should be provided with a simple and timely means to access and obtain their individually identifiable health information in a readable form and format.
- Correction- Individuals should be provided with a timely means to dispute the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied.

#### Others

- <sup>2</sup> In creating the HHS Privacy and Security Framework Principles, ONC relied on the Markle Foundation's core principles for a networked environment, among other available privacy and security principles. See "The Architecture for Privacy in a Networked Environment." Markle Connecting for Health Common Framework.
- <sup>3</sup> "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information. U.S. Department of Health and Human Services. December 15, 2008.



#### NCVHS NHIN Consent Recommendations (2006-2008)<sup>4</sup>

- Individuals should have the right to decide whether they want to have their personally identifiable electronic health records accessible via the NHIN.
- HHS should assess the desirability and feasibility of allowing individuals to control access to the specific content of their health records via the NHIN, and, if so, by what appropriate means.
  - If individuals are given the right to control access to the specific content
    of their health records via the NHIN, the right should be limited, such as by
    being based on the age of the information, the nature of the condition or
    treatment, or the type of provider.
- Individuals should be permitted to sequester specific sections of their health record in one or more predefined categories (e.g. genetic info, mental health info, substance abuse info)
- If information has been sequestered, a notation should denote this fact.



### With Laws & Principles to Guide Them, HIEs Across the Country Have Begun Implementing Different Consent Models



















NeHII

## Chris Henkenius Bass & Associates, Inc.







#### Community Betterment through HIE

#### NeHII, Inc. Nebraska Health Information Initiative

Chris Henkenius

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### Overview

- What is NeHII
- Project Milestones
- Privacy and Security
- Questions





### What is NeHII

- State-Wide Health Information Exchange
  - Connects hospitals, physicians, labs, pharmacies, and payers under same integration engine
- Provides electronic medical records to physicians who do not have them
  - EMRLite w/eRx
- Community Betterment Initiative



#### What is NeHII

- One of the first state-wide HIEs in the country
- One of the largest HIEs in the country
  - 4 health systems in the pilot
- One of the first to offer full functionality
  - Referral, Query, eRx
- One of the most efficient in the country
  - Full state-wide implementation \$8.54M







### NeHII, Inc. Implementation

- Hybrid federated model
  - Data providers use EdgeServers
  - Each data provider has own EdgeServer
  - Data populated via HL7 through VPN
- Provider Access via Internet (ASP model)
- Indexing within Interoperability Hub
  - MPI (master patient index)
  - RLS (record locator service)
- Eligibility verification



### Significant Milestones Achieved

- June 2007: Project plan and charter
- Oct. 2007: RFP released
- Jan. 2008: RFP responses received
- March 2008: Vendor demos
- April 2008: Articles of Incorporation filed with election of officers
- June 2008: Santa Cruz site visit
- July 2008: LOI with Axolotl

### Significant Milestones Achieved

- August 2008: <a href="www.nehii.org">www.nehii.org</a> released
- Sept. 2008: CEO site visit to Rochester, NY RHIO
- Oct. 2008: Axolotl User Group presentation, business plan version 3.1
- Nov. 2008: Executed agreement with Axolotl & security/privacy policies finalized



### Significant Milestones Achieved

- January 2009 Data Migration Work Commences
- February 2009 Operational Manual Created
- March 2009 Pilot Begins
- July 2009 Statewide Implementation







- Licenses
  - Type
    - Physician/Staff
    - Data Provider
      - Hospital
      - Office EMR
      - Health Plan
      - Lab/Radiology
    - HIE/RHIO
      - Subscription
      - Transaction
- Based on size of facility







- Privacy & Security Committee
  - Officers from participating facilities
  - Committee of the Board
  - Meets monthly
- Privacy & Security Policies
  - Developed by committee
  - Based off national standards
  - Fully audited
  - Available for free under license agreement







- Opt Out
  - All patients have right to opt out
    - 1.5% 2.0% Opt-out Rate
    - Global all in or all out
    - No time limit
  - Opt Out done via Patient Brochure
    - Brochures available at point of care and via Website
    - Phone, email, or file
  - All patients have right to opt back in
    - Stricter process
    - 600+ have opted back in







- Uses
  - Treatment
  - Payment
  - Public Health Reporting
  - PHRs
- Break the Glass
  - Not today, stay tuned





- Exclusions
  - Nebraska state law
    - LB702
  - lowa state law
  - "Other" state laws
- Applicability
  - Tied to participation agreement
  - Applies to all NeHII transactions
    - Applies to all Nebraska transactions
- Privacy and Security Officer





### NeHII, Inc. Contact Information

- Dr. Harris Frankel
- Deb Bass
- Chris Henkenius
- www.nehii.org







### NeHII, Inc. Bass & Associates, Inc.

#### Contact Information

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#### **VHIE**

Steve Larose, VP for External Affairs Vermont Information Technology Leaders, Inc.

Anne Cramer, Esq.
Primmer Piper Eggleston & Cramer PC





# Privacy and Security Policies Development Process

Steve Larose, VP for External Affairs
Vermont Information Technology Leaders, Inc.

Anne Cramer, Esq.
Primmer Piper Eggleston & Cramer PC



#### **About VITL**

- A private, non-profit 501(c)(3) organization. Operates as a public-private partnership.
- Funded by state government, Vermont Health IT Fund, and federal grants
- Incorporated on July 22, 2005
- Governed by board of 11, representing health care providers, government, employers, health plans, and consumers
- Operator of exclusive statewide HIE



### **Pilot Projects**

- Medication Claims History Service, launched April 2007
  - 2005-2006 Privacy & Security Volunteer Advisory Workgroup developed Participation Consent, Policies and Agreements
  - Patients who present to hospital ED asked for signed consent to access medication claims history
  - 95% do consent to access
- Lab results delivery service, launched Sept.
   2008
  - No separate patient consent required, as results not shared between provider organizations



# Public Engagement Process for HIE Policies

- Began in April 2008
- Invited consumer advocates and health care providers to participate
- Held six monthly face-to-face meetings
- Explored privacy and security issues, discussed concerns and learned positions of various groups



#### **Policies Drafted**

- After final public meeting, VITL staff and consultants considered concerns raised
- Outlined series of six policies to draft
  - Patient consent to opt in
  - Participating provider obligations
  - Secondary use prohibition
  - Response to breaches
  - Information security
  - Auditing and monitoring



#### **Patient Consent**

- Opt-in model considered necessary to meet Vermont Patient Privilege Statute, opt-out not an option
- Patient consent procedure was most contentious issue in public engagement meetings
  - Patient advocates wanted maximum patient control over who sees what data
  - Health care providers wanted maximum access to patient data with minimum effort
- VITL staff and consultants proposed compromise
  - If patient opts in initially, each provider to ask patient for permission before accessing data in HIE
  - Compromise was later rejected by VITL Board



#### **Comments Gathered**

- Draft policies circulated to those who participated in monthly meetings, plus larger mailing list
- Comments received and considered by VITL staff and consultants
- Revised drafts circulated and additional comments received for consideration



#### VITL Board Action

- Draft policies sent to VITL Board in Nov. 2008
- Board chose to conduct own review, formed subcommittee of VITL Board members
- Subcommittee met several times. Revised drafts considered OCR Dec. 2008 Guidance and HITECH Act Feb. 2009 provisions. Recommendations made to full VITL Board with final policies adopted April 2009
- Revisions to policies adopted by full Board in Sept. and Dec. 2009



### Final Patient Opt-In Policy

- Patient given educational materials at primary care physician office, asked to opt-in
- If patient signs opt-in form, data sharing enabled between all participating treating providers
- No further permission is needed by providers to access data
- No data filtering for sensitive conditions
- No special procedures for minor's PHI (yet)
- Data includes mental health and substance abuse
- Consent expiration date only if PHI includes substance abuse treatment
- Patient can withdraw consent at any time, reminder sent every 5 years



### Secondary Use

- No access to data for marketing, employers, or uses other than treatment/payment/ operations without specific patient authorization
- Clinical researchers can apply to VITL for use of de-identified data
- Policy later modified to allow health plans to access data for use in quality review, if patient gives specific authorization



### Operationalization

- Patient education materials and consent forms being prepared
- Providers signing participation agreements
- Provider education materials being prepared
- Interfaces being built
- Go live expected in next several months in two pilot communities



#### More Information

- Policies available for download at VHIE.org
- Contact info
  - Steve Larose 802-223-4100, ext. 102 or <u>slarose@vitl.net</u>
  - Anne Cramer 802-864-0880, ext. 1271 or acramer@ppeclaw.com



## **MAeHC**

# Micky Tripathi President & CEO, MAeHC



#### **MISSOURI PRIVACY DISCUSSION**

**February 5, 2010** 



## MAeHC ROOTS ARE IN MOVEMENT TO IMPROVE QUALITY, SAFETY, EFFICIENCY OF CARE



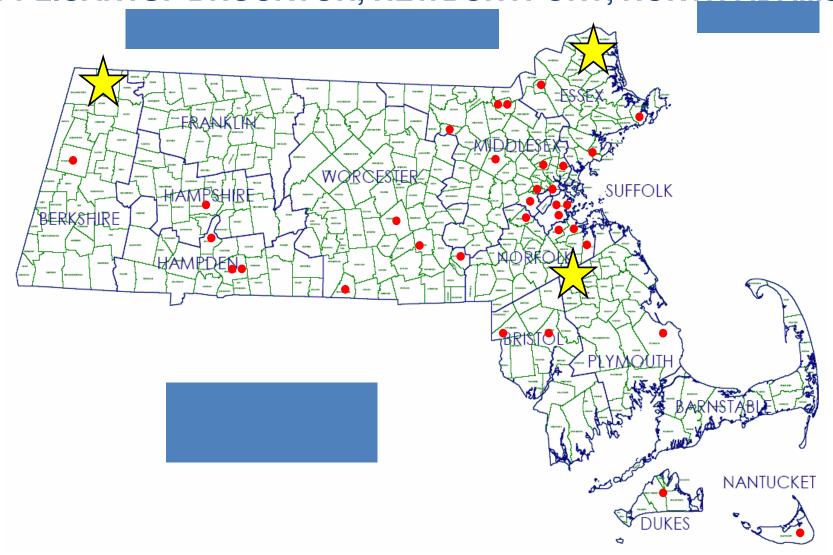




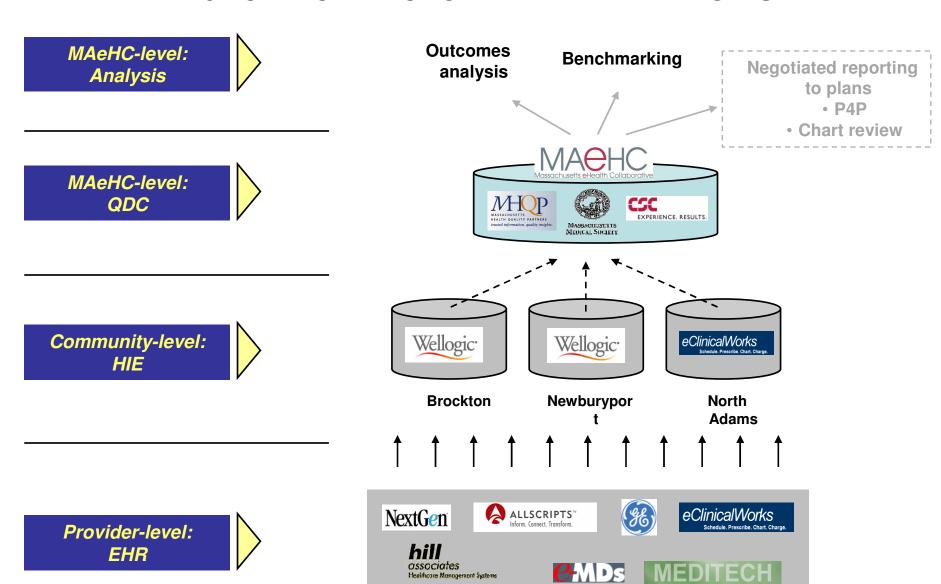


- Company launched September 2004
  - Non-profit registered in the State of Massachusetts
- CEO on board January 2005
- Backed by broad array of 34 MA health care stakeholders

### MAEHC SELECTED THREE PILOT SITES FROM 35 APPLICANTS: BROCKTON, NEWBURYPORT, NORTH ADAMS



#### MAeHC ARCHITECTURE AND DATA FLOWS















#### **Doctor's Office Record:**

- Private Office Notes
- Consultation Letters
- Scanned Reports
- Non-consented items

Vital information from each eHealth Record will be pulled from each of your doctor's offices. It will be encrypted for security and then sent to your eHealth Summary. It will not contain all of the information from your eHealth Record—just vital information that is critical for your care.



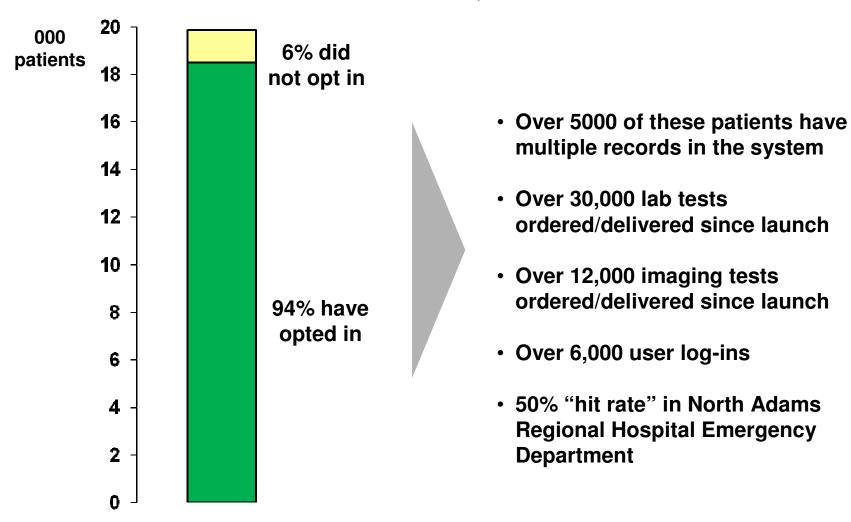


#### **The eHealth Summary:**

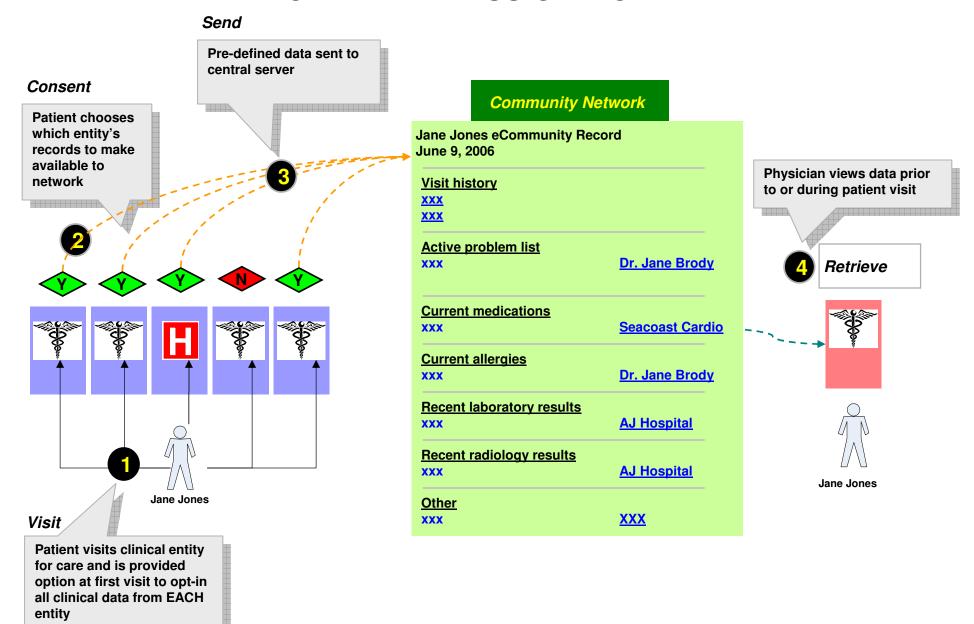
- Medication List
- Problem List
- Procedures
- Social History
- Allergies
- Past Medical History
- Family History
- Lab Results
- Radiology Results
- Immunizations

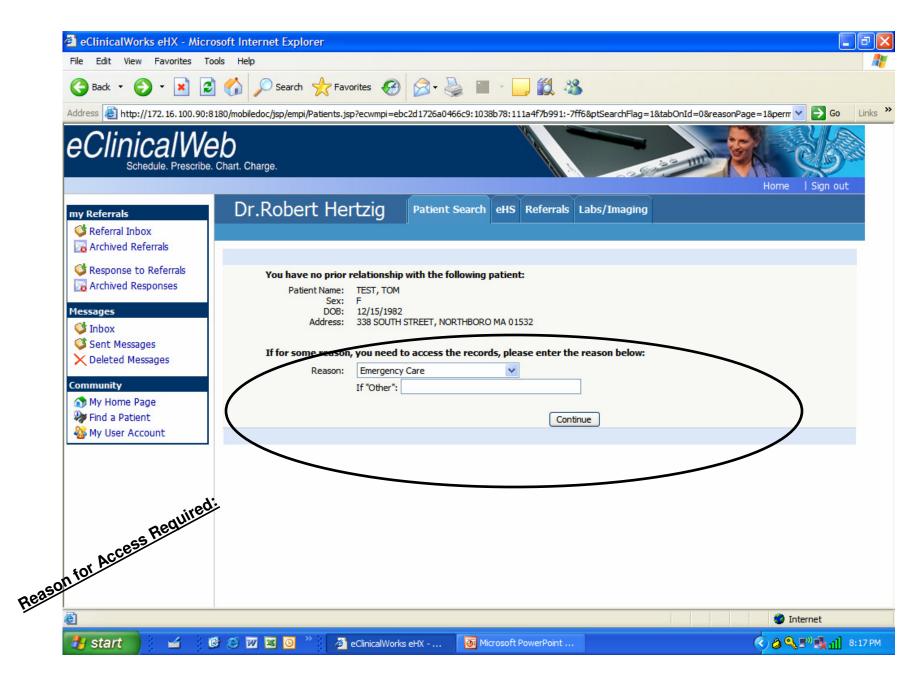
#### **OPT-IN RATE FOR OVER 25,000 PATIENTS**

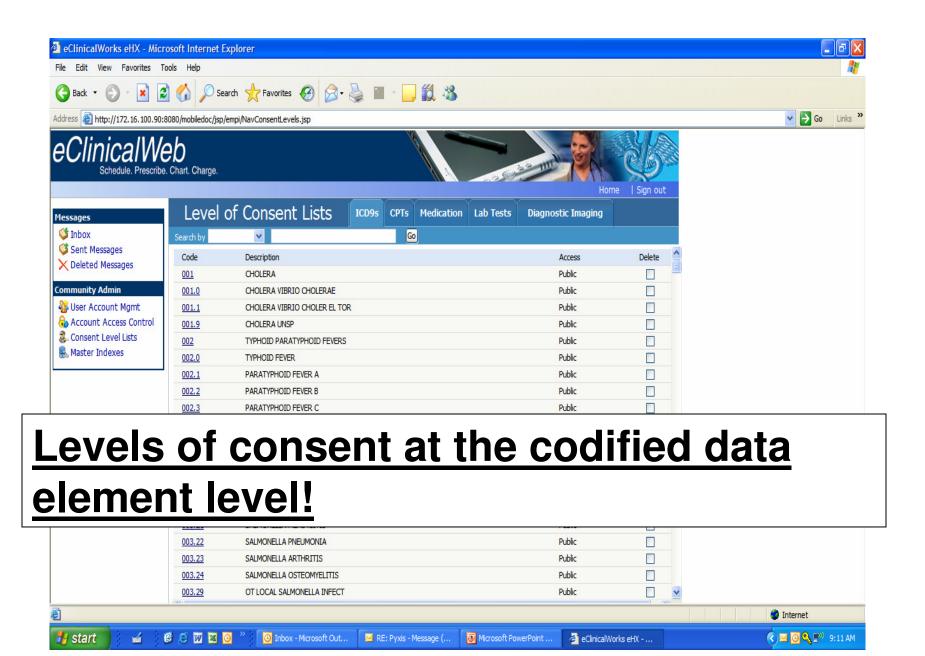
North Adams, March 2008



#### **OPT-IN PERMISSION MODEL**









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## **Appendix**



## Comparative Analysis of Select State Consent Policies

	Policies Apply Statewide?	Health Records Available through HIE?	Utilizes Model Statewide Form?	How Were Policies Developed & How Are They Enforced?
VT	Yes. VT operates a statewide HIE called the VT Health Information Exchange ("VHIE") operated by VT Info Tech Leaders ("VITL"). It is the only HIE in the state.	All PHI as defined under HIPAA is eligible to be included.     Currently exchange a standard CCD document	Yes. VITL provides patient consent and withdrawal forms to physician practices and other HIE participants.	<ul> <li>Policies developed by VITL staff and board members.</li> <li>Participants must comply as a condition of participation in VHIE.</li> </ul>
RI	> Yes. RI operates a statewide HIE called "currentcare." It is the only HIE in the state.	currentcare currently includes lab and pharmacy data.     Intent is for all information for which exchange standards exist to be available through the HIE.	> Yes.Currentcare provides form.	Codified in state law (RI HIE Act of 2008).      Participants must also comply with policies as a condition of participation in currentcare.
MA	No. Policies applied only to the 3 MAeHC pilot HIEs, which did not cover the entire state. The MAeHC pilot program has concluded. There are other HIEs in the state to which these policies did not apply.	<ul> <li>"Shared Health Summary," which included: medication list, problem list, diagnosis, immunizations, allergies, smoking status, vital signs, procedures, lab results, &amp; radiology results.</li> <li>Sensitive health information was included.</li> </ul>	> No.	<ul> <li>Policies developed and agreed to by the pilots through a collaborative process.</li> <li>Pilots agreed to comply with them as a condition of receiving grant funding under the MAeHC pilot program.</li> </ul>
NY	Yes. Policies apply to all HIEs participating in the Statewide Health Information Network of NY ("SHIN- NY") and receiving state grant funds under the HEAL-NY program.	Depends on the HIE.     Statewide policies do not proscribe any restrictions on the types of records that may be exchanged. Policies suggest that HIEs assess the legal risks of making records of federally assisted alcohol and substance abuse treatment centers (42 CFR Part 2) available through the exchange.	<ul> <li>Yes. Changes require approval of the Department of Health.</li> </ul>	<ul> <li>Policies developed by stakeholders through a consensus-driven process.</li> <li>HIEs must comply with policies as a condition of receiving grant funding under the HEAL-NY program.</li> </ul>
MN	Yes. There are currently two operational HIEs in MN. The consent policy described here applies to/serves as a baseline for both.	The state statute governing HIE defines health records as any information that relates to the past, present, or future physical or mental health or condition of a patient.  HIEs are free to determine what records to include/exclude from exchange.	≻ No.	Codified in state law (MN Health Records Act)      HIEs must comply with state law when developing their own consent policies.
ME	> Yes. ME operates a statewide HIE called "HealthInfoNet." It is the only HIE in the state.	Labs, imaging reports, prescriptions, allergies, discharge summaries, operative and consultant reports, problem lists, office visit notes.      Information from substance abuse treatment facilities (42 CFR Part 2) and mental health providers as well as HIV test results and psychotherapy notes are excluded.	<ul> <li>Yes.</li> <li>HealthInfoNet posts optout form on website.</li> <li>Providers may also provide forms to patients at provider sites.</li> </ul>	State law governing consent for disclosure of health records was amended to explicitly allow disclosure to a HIE for specified purposes without consent as long as patients could opt-out.      Participants must comply with policies as a condition of participation in HealthInfoNet.
ne i a n a		Lab & x-rays, medication & immunization history, transcribed diagnostic & treatment records, allergies & drug interactions, & other transcribed clinical reports created after NeHII's start date.      Records related to alcohol & substance abuse treatment programs, emergency protective custody proceedings, genetic testing, HIV testing, and mental health treatment	NeHII maintains opt-out form on website.      Forms may be provided by and returned to participant sites.	Policies were developed by NeHII's Privacy     & Security Workgroup (a committee of the     NeHII Board).      Participants must comply with policies as a     condition of participation in NeHII.
EAL		ses @alyxcNotaor distribution		49

## Comparative Analysis of Select State Consent Policies

	Opt-in or Opt- out?	Can Patients Control Whether & Which Providers May Make Records Available through the Exchange?	Can Patients Control What Types of Records Providers Make Available through the Exchange?	Can Patients Control Whether and Which Providers May Access Records through the Exchange?	Can Patients Control What Types of Records Providers May Access through the Exchange
VT	In	Yes. Patient consent is required to enable data sharing between providers. Once opt-in given, any treating participating provider may make records available through the HIE.	No. All of a provider's records that fall within the scope of the information included in the exchange are made available.	Yes. Patient consent is required to enable data sharing between providers. Once opt-in given, any treating participating provider may access records available through the HIE.	> No.
RI	In	<ul> <li>Yes. Patient consent is required before providers may make records available.</li> <li>By enrolling in currentcare, patients grant consent to all of their treating participating providers (at once) to make their information available.</li> </ul>	No. All of a provider's records that fall within the scope of the information included in the exchange are made available.	<ul> <li>Yes. Patient consent is required before providers may access available records.</li> <li>Patients may grant this consent on a provider by provider basis.</li> <li>Patients may also grant consent to all treating providers only in an emergency.</li> </ul>	> No.
МА	In	<ul> <li>Yes. Patient consent was required before providers could make records available.</li> <li>Patients were able to grant this consent on a provider by provider basis.</li> </ul>	<ul> <li>All of a provider's records that fell within the scope of the information included in the exchange (the "Shared Health Summary") were made available.</li> <li>However, certain sensitive information (HIV and genetic test results) required a patient's consent each time it was made available.</li> </ul>	<ul> <li>No. All treating participating providers could access available records.</li> </ul>	> No.
NY	ln	> No.	> No.	<ul> <li>Yes. Patient consent is required before providers may access available records.</li> <li>Patients may grant this consent on a provider by provider basis.</li> </ul>	> No.
MN	Hybrid	No. If a patient's identifying information is included in a RLS, the patient can't control which providers may make their records available through the exchange. Patients may, however, opt-out of having their identifying information in a RLS, thereby opting out of the exchange entirely.	<ul> <li>Not required by the statute</li> <li>Different HIEs free to set policies at their discretion.</li> </ul>	<ul> <li>Yes. Patient consent is required before providers may access available records (and before they may search for a patient in a RLS).</li> <li>Patients may grant this consent on a provider by provider basis.</li> </ul>	<ul> <li>Not required by the state statute.</li> <li>Different HIEs free to set policies at their discretion.</li> </ul>
ME	Out	> No.	≻ No.	≻ No.	> No.
NE	Out	> No.	≻ No.	≻ No.	> No.
M A N H E A I SOLUT	T H IONS	For discussion purposes only	- Not for distribution		50

## Comparative Analysis of Select State Consent Policies

	What Uses Are Permitted by Consent? If Additional Uses, What are the Attendant Requirements?	Duration/Revocation	How is consent to make available and/or access records about services to which a minor consented on his/her own obtained?	Is Emergency Access (Break the Glass) Permitted?
Vī	<ul> <li>TPO as defined under HIPAA.</li> <li>"Quality Review" by health plans, insurers or other 3rd party payers with specific patient authorization.</li> <li>De-identified data may be used for research, QI and public health.</li> </ul>	<ul> <li>Until revoked (if no expiration date).</li> <li>Consents for providers to release records covered by 42 CFR Part 2 must have an expiration date.</li> <li>Patients receive reminder every 5 years that they have right to withdraw consent.</li> </ul>	> Under consideration.	> N/A.
RI	<ul> <li>Coordination of care and public health (broadly defined in statute)</li> </ul>	> Until revoked.	<ul> <li>Records for minors are made available and accessed based on parents' consent.</li> </ul>	> Yes.
MA	<ul> <li>TPO</li> <li>Quality improvement, and business operations.</li> </ul>	Two years.      Consents can be revoked at will.	<ul> <li>Records for minors between select ages were excluded from exchange.</li> </ul>	> N/A.
NY	<ul> <li>Level1: Treatment, quality improvement, care management, and insurance coverage reviews.</li> <li>Level 2: Any uses of PHI other than Level 1 uses, including but not limited to payment, research and marketing.</li> </ul>	Consent for Level 1 uses: until revoked.      Consent for Level 2 uses: must be time-limited & expire no more than 2 years after execution unless a longer duration is required to complete a research protocol.	> Records for minors age 10 & over are excluded from exchange.	> Yes.
MN	<ul> <li>Not addressed by the statute.</li> <li>Different HIEs free to set policies at their discretion.</li> </ul>	Consent to access clinical information: 1 year unless a lesser period is specified in the consent or otherwise required by law.      Consent to make patient identifying information available to RLS: No expiration	<ul> <li>Not addressed by the statute.</li> <li>Different HIEs free to set policies at their discretion.</li> </ul>	Yes. Providers may access a RLS and available clinical records without consent in an emergency. If a patient has opted-out of the RLS, however, there will be no records available to view in an emergency.
ME	> Treatment.	> N/A	<ul> <li>Records for minors are included in the exchange unless the minor or his/her parent opts-out.</li> </ul>	N/A. If a patient has opted-out of the exchange, there will be no records available to view in an emergency.
NE	> Treatment and payment.	> N/A	<ul> <li>Information about STD testing or treatment of minors consented to by the minor is excluded from exchange.</li> </ul>	<ul> <li>No by choice. Information about patients who opt-out is available but not accessible.</li> </ul>

